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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,453	07/29/2003	Rossella Musa	241019US0DIV	4847
22850	7590	10/20/2004		EXAMINER
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				OH, SIMON J
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/628,453	MUSA ET AL.
	Examiner Simon J. Oh	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11,14,15 and 17-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 11,14,15 and 17-36 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/926,105.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 14, 15, and 17-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth (U.S. Patent No. 6,153,224) and Sarlikiotis *et al.* (U.S. Patent No. 6,284,287)

The Staniforth patent teaches a process for treating inhaler carrier particles in order to allow a higher respirable fraction of the active substance (See Abstract). The carrier particles are preferably lactose particles, such as alpha lactose monohydrate (See Column 4, Lines 35-41; and Example 1, Column 10, Line 67). The preferred range of particle sizes lie in the range of 60 microns to 180 microns; Example 1 uses particles in the range of 90 microns to 125 microns (See Column 4, Lines 42-57; and Column 11, Lines 3-22). The carrier particles include additives, which promote the release of the active substance particles from the carrier particles upon actuation of the inhaler (See Column 3, Lines 3-6). Suitable additive materials include stearic acid, magnesium stearate, and sodium stearyl fumarate (See Column 5, Lines 36-55). In most cases, the amount of additives does not exceed more than 2% by weight (See Column 4, Lines 6-14). The mass median diameter of the active substance particles is preferably less than 5 microns (See Column 7, Lines 36-43). Suitable active substances disclosed by the patent include

salmeterol, salbutamol, ipratropium bromide (See Column 7, Lines 44-64), and beclomethasone dipropionate (See Example 1, Column 11, Line 43). The patent also discusses the treatment of the carrier particles in order to alleviate surface irregularities. In the course of the treatment, asperities of the carrier particles are removed as smaller grains and attach themselves to high surface energy sites, without significantly changing the particle size of the carrier particles themselves (See Column 8, Lines 51-65; Column 9, Lines 6-37; and Column 10, Lines 1-27). The patent states that the carrier particles are treated with the addition of the additives, and may be mixed for 0.1 hours to 0.5 hours (6 to 36 minutes), using a tumbling blender, such as a Turbula Mixer (See Column 8, Lines 47-50; and Example 1, Column 11, Lines 23-28).

Alternatively, the carrier may be treated alone, before the addition of any additive; or with the addition of both the additive and the active substance (See Column 8, Line 66 to Column 9, Line 5). The treatment may also be carried out in a mill, such as a ball mill, for a period of time ranging from 0.25 hours (15 minutes) to 6 hours (360 minutes) (See Column 9, Lines 38-67).

Staniforth does not give a specific example where the treatment of the carrier particles is carried out for 30 minutes, nor does it teach the use of a sigma blade mixer, running at a speed between 100 to 300 rpm.

The Sarlikiotis *et al.* patent teaches a formulation for use in an inhaler, which comprises active substance particles coating carrier particles. Substances suitable as carrier particles include lactose, as well as its derivatives (See Column 4, Lines 14-16). The active substance used should have a particle size of 0.01 microns to 10 microns in order to ensure sufficient attraction to the carrier particles (See Column 2, Lines 61-64). The list of suitable active substances include ipratropium bromide, oxytropium bromide, beclomethasone, budesonide,

flunisolide, formoterol, salbutamol, salmeterol, and terbutalin; esters of the drugs may be used as well, including dipropionate (See Column 3, Lines 24-65). Preparation of the formulation is carried out in a mixer, such as a tumble mixer, a rotary mixer, or a high-speed mixer; the Turbula Mixer is given as an example of a tumble mixer (See Column 4, Lines 32-37). Both the active substance and the carrier particles are mixed in the mixer until the carrier particles are coated with the active substance, with "the fine fraction gradually disappearing and round, coated particles resulting" (See Column 4, Lines 38-41). Examples are given where the preparation is carried out in a mixer, for 30 minutes (See Examples 1 and 2).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Staniforth in view of Sarlikiotis *et al.* Sarlikiotis *et al.* teach a mixing time of 30 minutes, as well as an expanded list of suitable active substances. Furthermore, it would be obvious that the mixing process described in Sarlikiotis *et al.* would modify the surface properties of the carrier particles, as described in Staniforth. It is the opinion of the examiner that there is no criticality to the limitations of Claim 20, as the formulation of inhaler particles with improved surface properties is successfully carried out, as shown in Staniforth and Sarlikiotis *et al.*, without the specific use of a sigma blade mixer running at 100 to 300 rpm. Thus, the invention, as a whole, is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 14, 15, and 17-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,641,844. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to processes for the modification of surface properties of particles for use as carrier particles for the pulmonary administration of micronized drugs by means of dry powder inhalers. In certain embodiments of both processes, the carrier particles consist of α -lactose monohydrate. In other embodiments of both processes, the starting diameter of the carrier particles lies between 90 and 150 μm . Both processes also use the same broad group of active ingredients and the same broad group of lubricants.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sjo

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